



49076.000004.UTL2

U.S. PATENT

## UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of ) Group Art Unit: 1642  
LEDBETTER )  
Serial No.: 10/053,530 ) Examiner: Helms, Larry Ronald  
Filed: January 17, 2002 ) Confirmation No.: 8993  
For: BINDING DOMAIN )  
IMMUNOGLOBULIN FUSION )  
PROTEINS )

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)(3)

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with Applicant's duty under 37 C.F.R. § 1.97-98, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08 and copies are enclosed for the convenience of the Examiner. Please note, some of the references listed on the accompanying PTO/SB/08 form have come to applicant's attention in a communication from a foreign patent office (International Search Report attached hereto, as well as a European Search Report) in a counterpart foreign application. Applicant is submitting the International Search Report and the European Search Report from the International Searching Authorities for this purpose.

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 C.F.R. § 1.56 and the submission thereof by Applicant shall not be construed as an admission that any such patent, publication or other information referred to

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therein is material or considered to be material (37 C.F.R. § 1.97(h)), or even qualified as "prior art" under 35 U.S.C. § 102 with respect to this invention unless specifically designated by Applicant as such.

The attached Information Disclosure Statement is being filed in accordance with 37 CFR §§ 1.97(c) and 1.98. This Information Disclosure Statement is being filed after an action on the merits but before a Final Action under § 1.113 or a Notice of Allowance under § 1.113.

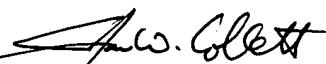
The fee of \$180.00, pursuant to 37 CFR § 1.17(p) is due in connection with this filing.

The Commissioner is authorized to debit this amount and any additional fees required by this paper or credit any overpayment to Deposit Account No. 02-4553.

Respectfully submitted,

BUCHANAN INGERSOLL L.L.P.

By:

  
James W. Collett, Ph.D.  
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PTO/8B/21 (02-04)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM  (to be used for all correspondence after initial filing)	Application Number	10/053,530	
	Filing Date	January 17, 2002	
	First Named Inventor	LEDBETTER	
	Art Unit	1642	
	Examiner Name	Helms, Larry Ronald	
Total Number of Pages in This Submission	26	Attorney Docket Number	49076.000004.UTL2

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): PTO/SB/08A (5 pages); 71 references; Return Postcard
Remarks		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	James W. Collett, Ph.D.
Signature	
Date	May 24, 2004

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Barbara J. Kielt
Signature	
Date	May 24, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# FEET TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$ 180.00)

## Complete if Known

Application Number	10/053,530
Filing Date	1/17/02
First Named Inventor	LEDBETTER
Examiner Name	HELM 6
Art Unit	1642
Attorney Docket No.	49076.000004.0722

## METHOD OF PAYMENT (check all that apply)

Check  Credit card  Money Order  Other  None

Deposit Account:

Deposit Account Number: 02-4553  
Deposit Account Name: BUCHANAN INGERSOLL P.C.

The Director is authorized to: (check all that apply)

Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
<b>SUBTOTAL (1) (\$)</b>			

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	-20** =	X	=	Fee from below	Fee Paid
Independent Claims	- 3** =	X	=		
Multiple Dependent			=		

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1202 18	2202 9	Claims in excess of 20	
1201 86	2201 43	Independent claims in excess of 3	
1203 290	2203 145	Multiple dependent claim, if not paid	
1204 86	2204 43	** Reissue independent claims over original patent	
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent	
<b>SUBTOTAL (2) (\$)</b>			

\*\* or number previously paid, if greater; For Reissues, see above

### 3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	
Other fee (specify)			
*Reduced by Basic Filing Fee Paid			
<b>SUBTOTAL (3) (\$)</b>			180.00

(Complete if applicable)

Name (Print/Type)	JAMES W. COLLETT, Ph.D.	Registration No. (Attorney/Agent)	46,636	Telephone (619) 578-5000
Signature	<i>J. W. Collett</i>			
Date	5-24-04			

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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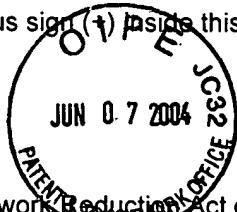
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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/053,530
				Filing Date	1/17/02
				First Named Inventor	Ledbetter
				Group Art Unit	1642
				Examiner Name	Helms
Sheet	1	of	5	Attorney Docket No	49076.000004.UTL2

U. S. PATENT DOCUMENTS						
Examinee Initials*	Cite No. <sup>1</sup>	U. S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
A.	5,098,833			LASKY et al.	03/24/92	
B.	5,260,203			LADNER et al.	11/09/93	
C.	5,434,131			LINSLEY et al.	07/18/95	
D.	5,455,030			LADNER et al.	10/03/95	
E.	5,521,288			LINSLEY et al.	05/28/96	
F.	5,580,756			LINSLEY et al.	12/03/96	
G.	5,605,690			JACOBS et al.	02/25/97	
H.	5,637,481			LEDBETTER et al.	06/10/97	
I.	5,709,859			ARUFFO et al.	01/20/98	
J.	5,714,147			CAPON et al.	02/03/98	
K.	5,770,197			LINSLEY et al.	06/23/98	
L.	5,773,253			LINSLEY et al.	06/30/98	
M.	5,844,095			LINSLEY et al.	12/01/98	
N.	5,869,049			NOELLE et al.	02/9/99	
O	5,876,718			NOELLE et al.	03/02/99	
P	5,916,560			LARSEN et al.	06/29/99	
Q.	6,087,329			ARMITAGE et al.	07/11/00	
R.	6,090,914			LINSLEY et al.	07/18/00	
S.	6,194,551 B1			IDUSOGIE et al.	02/27/01	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document by the two-letter code (WPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Examiner Signature	Date Considered
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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/053,530
(use as many sheets as necessary)				Filing Date	1/17/02
				First Named Inventor	Ledbetter
				Group Art Unit	1642
				Examiner Name	Helms
Sheet	2	of	5	Attorney Docket No.	49076.000004.UTL2

U. S. PATENT DOCUMENTS					
Examinee Initials*	Cite No. <sup>1</sup>	U.S. Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
				MM-DD-YYYY	

T.	6,264,951 B1	ARMITAGE et al.	07/24/01	
U.	6,312,692 B1	NOELLE et al.	11/06/01	
V.	6,376,459 B1	ARUFFO et al.	04/23/02	
W.	6,384,198 B1	DIEGEL et al.	05/07/02	
X.	6,410,319 B1	RAUBITSCHEK et al.	06/25/02	
Y.	6,444,792 B1	GRAY et al.	09/03/02	
Z.	6,472,510 B1	ARUFFO et al.	10/29/02	
AA.	6,623,940 B1	LEDBETTER et al.	09/23/03	
AB.	6,641,809 B1	LINSLEY et al.	11/04/03	
AC.	2001/004135 A1	STAHI et al.	11/22/01	
AD.	2002/0031510 A1	LARSEN et al.	03/14/02	
AE.	2002/0039557 A1	WHITE	04/04/02	
AF.	2002/0155604 A1	LEDBETTER et al.	10/24/02	
AG.	2003/0219436 A1	LEDBETTER et al.	11/27/03	
AH.	2003/0219446 A1	LINSLEY et al.	11/27/03	
AI.	2003/0219876 A1	LEDBETTER et al.	11/27/03	
AJ.	2004/0058445 A1	LEDBETTER et al.	03/25/04	

FOREIGN PATENT DOCUMENTS					
Examinee Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of cited Document MM-DD-YYYY
		Office <sup>3</sup>	Kind Code <sup>5</sup> Number <sup>4</sup> (if known)		
AK.	WO	92/00092		BRISTOL-MYERS SQUIBB COMPANY	01/09/92
AL	WO	93/00431		BRISTOL-MYERS SQUIBB COMPANY	01/07/93
AM	WO	99/42077		XCYTE THERAPIES, INC.	08/26/99

Examiner Signature		Date Considered	
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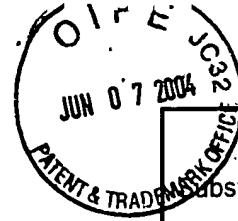
				Complete if Known	
				Filing Date	1/17/02
				First Named Inventor	Ledbetter
				Group Art Unit	1642
				Examiner Name	Helms
Sheet	3	of	5	Attorney Docket No.	49076.000004.UTL2

/	AN	EP	0 555 880 A2	BRISTOL-MYERS SQUIBB COMPANY	08/18/93		
/	AO	EP	0 757 099 A2	BRISTOL-MYERS SQUIBB COMPANY	07/21/95		
/	AP	EP	0 682 039 A1	BRISTOL-MYERS SQUIBB COMPANY	11/15/95		
/	AQ	EP	1 186 300 A1	BRISTOL-MYERS SQUIBB COMPANY			

#### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume- issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AICHER, et al., "Characterization of Human Inducible Costimulator Ligand Expression and Function", The Journal of Immunology, 2000, 164: 4689-4696	
		CARTER, "Improving the Efficacy of Antibody-Based Cancer", Nature, November 2001, Volume 1, 118-129	
		CLARK et al., "Structure, Function, and Genetics of Human B Cell-Associated Surface Molecules", Advances in Cancer Research, Vol. 52, 81-149	
		DAMLE, et al., "Direct helper T cell-induced B cell differentiation involves interaction between T cell antigen CD28 and B cell activation antigen B7", Eur. J. Immunology 1991; 21; 1277-1282	
		DAVIES, et al., "'Camelising' Human Antibody Fragments: NMR Studies on VH Domains," FEBS Letters 339 (1994) 285-290	
		DESMYTER et al., "Crystal structure of a camel single-domain V <sub>H</sub> antibody fragment in complex with lysozyme", Nature Structural Biology, Volume 3, Number 9, September 1996, 803-811	
		DIETSCH et al., "Coengagement of CD2 with LFA-1 or VLA-4 by bispecific ligand fusion proteins primes T cells to respond more effectively to T cell receptor-dependent signals, Journal of Leukocyte Biology, Volume 56, October 1994, 444-452	
		DIETSCH et al., "Bispecific receptor globulins, novel tools for the study of cellular interactions", Journal of Immunological Methods, 162 (1993) 123-132	
		DURIE et al., "Prevention of Collagen-Induced Arthritis with an Antibody to gp39, the Ligand for CD40", Science, Vol. 261, September 3, 1993, 1328-1330	

Examiner Signature		Date Considered	
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				Complete if known	
		Application Number		10/053,530	
		Filing Date		1/17/02	
		First Named Inventor		Ledbetter	
		Group Art Unit		1642	
		Examiner Name		Helms	
Sheet	4	5	Attorney Docket No		
49076.000004.UTL2					

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		FELL et al., "Genetic Construction and Characterization of a Fusion Protein Consisting of a Chimeric F(ab') with Specificity for Carcinomas and Human IL-2", <i>The Journal of Immunology</i> , Vol. 146, 2446-2452, No. 7, April 1, 1991			
		FILPULA et al., "Single-chain Fv designs for protein, cell and gene therapeutics" <i>Exp. Opin. Ther. Patents</i> (1999) 9 (3):231-245			
		GILLILAND et al., "Rapid and Reliable Cloning of antibody Variable Regions and Generation of Recombinant Single Chain Antibody Fragments", <i>Tissue Antigens</i> 1996: 47: 1-20 (Denmark)			
		HAYDEN, et al., "Antibody Engineering," <i>Curr. Opin. Immuno.</i> , 9:201-212 (1997)			
		HAYDEN, et al., "Single-chain Mono- and bispecific Antibody Derivatives With Novel Biological Properties and Antitumor Activity from a COS Cell Transient Expression System," <i>Thera. Immuno.</i> , 1:3-15 (1994)			
		HAYDEN et al., "Costimulation by CD28 sFv expressed on the tumor cell surface or as a soluble bispecific molecule targeted to the L6 carcinoma antigen", <i>Tissue Antigens</i> 1996: 48; 242-254			
		HU, et al., "Minibody: A Novel Engineered Anti-Carcinoembryonic Antigen Antibody Fragment (Single-Chain Fv-CH3) Which Exhibits Rapid, High-Level Targeting of Xenografts," <i>Cancer Res.</i> 56(13):3055-3061 (1996)			
		HUDSON, "Recombinant antibodies: a novel approach to cancer diagnosis and therapy", <i>Exp. Opin. Invest. Drugs</i> (2000) 9(6):1231-1242			
		HUDSON, "Recombinant antibody fragments", <i>Current Opinion in Biotechnology</i> , 1998, 9:395-402			
		KORTT, et al., "Dimeric and Trimeric Antibodies: High Avidity scFvs for Cancer Targeting," <i>Biomole. Eng.</i> , 18:95-108 (2001)			
		LEE et al., "Generation and characterization of a novel single-gene-encoded single-chain immunoglobulin molecule with antigen binding activity and effector functions", <i>Molecular Immunology</i> 36 (1999) 61-71			
		LI, et al., "Single-chain antibodies against human insulin-like growth factor I receptor: expression, purification and effect on tumor growth", <i>Cancer Immunol. Immunother.</i> (2000) 49:243-252			

Examiner Signature		Date Considered
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Substitute for form 1449B/PTO			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			
(use as many sheets as necessary)			
JUN 07 2004 JC32 OI P E PATENT & TRADEMARK OFFICE			
Sheet	5	5	Complete if known
			Application Number 10/053,530
			Filing Date 1/17/02
			First Named Inventor Ledbetter
			Group Art Unit 1642
			Examiner Name Helms
			Attorney Docket No 49076.000004.UTL2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume- issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LIU, et al., "Production of a Mouse-Human Chimeric Monoclonal Antibody to CD20 With Potent Fc-Dependent Biological Activity," <i>J. Immunol.</i> 139(10):3521-3526 (1987)	
		MULTANI et al., "Monoclonal Antibody-Based Therapies for Hematologic Malignancies", <i>Journal of Clinical Oncology</i> , Vol. 16, No 11 (November), 1998: pp 3691-3710	
		PARK et al., "Generation and Characterization of a Novel Tetravalent Bispecific antibody that binds to hepatitis B virus surface antigens", <i>Molecular Immunology</i> 37 (2000) 11-23-1130	
		SEGAL et al., "Introduction: bispecific antibodies", <i>Journal of Immunological Methods</i> , 248 (2001) 1-6	
		SHU et al., "Secretion of a single-gene-encoded immunoglobulin from myeloma cells", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 90, 7995-7999, September 1993	
		SOURIAU et al., "Recombinant antibodies for cancer diagnosis and therapy", <i>Expert Opin. Biol. Ther.</i> (2003) 3(2):305-318	
		SPORICI et al., "ICOS Ligand Costimulation Is Required for T-Cell Encephalitogenicity", <i>Clinical Immunology</i> , Vol. 100, No. 3, September, pp. 277-288,2001	
		WU et al., "Multimerization of a Chimeric Anti-CD20 Single-chain Fv-Fc Fusion Protein is Mediated Through Variable Domain Exchange," <i>Protein Eng.</i> ,14(12):1025-1033 (2001)	

Examiner Signature		Date Considered
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